

REMARKS

Claims 1-20 and 26 were examined. Claims 1 and 11 are amended. Claims 1-20 and 26 remain in the Application.

A. After Final Amendments

Applicant amends claim 1 to describe a lumen extending through the elongate member from a proximal end to a distal end. Applicant believes the amendment is fully supported in the Application at, for example, pages 4-5 where embodiments of a needle to be used with an intracardiac catheter or intravascular catheter in delivering treatment agents are described. Applicant also amends claim 11 and adopts the Patent Office's suggestion. Applicant respectfully requests that the claim amendments be entered.

B. Objection to Claim 11

Claim 11 is objected to because of an informality. Applicant amends Claim 11 according to the suggestion presented by the Patent Office. Applicant respectfully requests that the Patent Office withdraw the objection.

C. Claims Rejected Under 35 U.S.C. §103

Claims 1-3, 5-9, 11-12, 14-20, and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay, et al. ("Tay") in view of U.S. Patent No. 6,539,792 to Lull, et al. ("Lull").

Independent Claim 1 is patentable over the cited references for at least the reasons that the cited references do not teach or suggest an elongated member having a dimension suitable for insertion into a body, a distal opening, and a lumen extending from a proximal end to the distal opening and in communication with the opening to allow a substance to be delivered through the lumen and out of the opening. According to Claim 1, for example, the elongated member may have a lumen in contact with a distal aperture so that a drug, pharmaceutical agent, fluid, protein, polypeptide, gene therapy material, cell therapy material, and/or deoxyribonucleic acid (DNA)

can be injected into a vessel or tissue of a person at a proximal end of the elongate member and out the distal opening.

Tay teaches an apparatus for closing and sealing a vascular puncture by generating sufficient heat to fuse the vascular tissue together. (See Abstract). Tay teaches that the puncture may have previously been caused by a needle or similar device. (See paragraph 1, lines 35-47; col. 5, lines 15-18; and col. 5, lines 40-45). However Tay teaches that the needle or similar device is removed prior to inserting a cautery probe, such as a probe tipped with cauterizing electrodes to cauterize tissue surrounding the puncture, and optionally having coils of temperature-dependent resistant wire on the probe. (See col. 1, lines 40-41; col. 5, lines 21-62; col. 20, lines 42-54; and Figures 10-11, 19-20, and 26-32). Moreover, Tay describes the cautery probe as a monopolar electrode or bipolar electrode probe connected to a power supply and having an inside containing insulation, electrodes for carrying enough current to cauterize tissue, and/or a guidewire disposed therethrough (see col. 15, lines 36 through col. 16, line 52). Specifically, although Tay allows for the possibility of blood flowing out of the puncture in the vessel and through insulation layer 137 and out of hole 138, Tay does not teach or suggest an opening sufficient to a substance in the opposite direction, such as a fluid delivered at a pressure greater than that of this blood flow. For instance, in Tay, the primary purpose is to seal the puncture and stop the blood flow. (See col. 15, lines 54 through col. 16, line 11; and Figure 20 and 28).

The Patent Office cites the embodiment shown in Figures 20 and 20A of Tay where the probe is introduced over a guidewire out hole 138. The lumen terminating in hole 138, however, does not extend from a proximal end to a distal end of the probe which the Patent Office identifies as the elongate member. Instead, it extends only partially through the probe.

Next, Lull teaches a method and apparatus for balancing resistance, such as to determine a mass flow rate of a gas or other fluid, in a pipe. (See Abstract, and col. 1, lines 10-50). Moreover, Lull teaches applications such as automotive applications, hot-wire anemometry, or other applications in which variations in the resistance of a leg of a resistive bridge circuit is indicative of a change in a property that varies with resistance. (See col. 17, lines 4-15). However, the Patent Office has not identified and Applicant is unable to find any teaching or suggestion in Lull of an elongated member having a dimension suitable for insertion into a body, a

distal portion suitable for insertion into tissue, a distal opening, and a lumen in communication with a distal opening to allow a substance to be delivered through the lumen and out of the opening, as required by amended claim 1.

Hence, since neither Tay, Lull, nor the combination teaches or suggests the above noted limitation of amended Claim 1, Applicant respectfully requests that the Patent Office withdraw the above rejection of Claim 1.

Claims 2-3 and 5-9 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated above, claims 2-3 and 5-9 are not obvious over the cited references. Applicant respectfully requests the Patent Office withdraw the rejection to claims 1-3 and 5-9.

Independent claim 11 is patentable over the cited references for at least the reason that the cited references do not teach or suggest a needle having dimension suitable for insertion into a body, and having a distal end capable of puncturing skin, as required by amended claim 11. Tay teaches a cautery probe for cauterizing a puncture in a vessel made by a needle, after the needle has been removed. However, Tay does not teach or suggest that the cautery probe has a distal end capable of puncturing skin as required by amended claim 11. The Patent Office cites col. 15, line 65 through col. 16, line 1 to support the conclusion that the probe in Tay can puncture tissue. The cited language, however, merely says the probe may be percutaneously inserted. It does not follow that it can puncture skin. It is appreciated that certain devices, such as a guidewires, are capable of percutaneous insertion without puncturing the skin. In the case of a guidewire, for example, access to a blood vessel is made by an introducer between the skin and the blood vessel. A guidewire is then inserted through the introducer. Finally, Lull does not teach a needle, as required by claim 11.

Hence, since neither Tay, Lull, nor the combination teach the above-noted limitation of amended Claim 11, Applicant respectfully requests the Patent Office withdraw the rejection above of Claim 11.

Claims 12, 14-20, and 26 from Claim 11 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 11, Applicant asserts claims 12, 14-

20 and 16 are not obvious over the cited references. Hence, Applicant respectfully requests the Patent Office withdraw the rejection to claims 11-12, 14-20 and 26 under 35 U.S.C. §103(a).

Claims 4 and 13 are rejected under 35 U.S.C. § 103(a) by Tay, Lull, and further in view of U.S. Patent No. 3,470,604 to Zenick (Zenick). Claims 4 and 13 are dependent claims as they depend on independent claims 1 and 11. Applicant submits that dependent claims 4 and 13, being dependent upon independent claims 1 and 11, are patentable over the cited references for the reasons explained above. Thus, Applicant respectfully requests that the Patent Office withdraw the rejection of dependent claims 4 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Tay, Lull, and further in view of Zenick.

Claims 10 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tay in view of Lull, and further in view of U.S. Patent No. 5,873,835 to Hastings et al. (Hastings). Applicant submits that claims 10 and 18, depending from claim 1, are patentable over Tay in view of Lull, and further in view of Hastings. Thus, Applicant respectfully requests that the Patent Office withdraw the rejection of dependent claims 10 and 18 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending (1) are in proper form, (2) are neither obvious nor anticipated by the relied upon art of record, and (3) are in condition for allowance. A Notice of Allowance is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,

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Date: 10/11/05

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I hereby certify that this correspondence is being transmitted by facsimile on the date shown below to the United States Patent and Trademark Office.

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Date